UNIVERSITAT POLITÈCNICA DE CATALUNYA
BARCELONATECH
Facultat d'Òptica i Optometria de Terrassa

GRAU EN ÒPTICA I OPTOMETRIA

TREBALL FINAL DE GRAU

A CLINICAL INVESTIGATION TO STUDY THE PRISMATIC STABILIZATION SYSTEM IN ASTIGMATIC SOFT CONTACT LENSES

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RESUM

English

There is a real need of effective stabilization systems in astigmatic contact lenses that ensure a comfortable and sharp vision. However, despite the important improvements that have been done in the last years, rotational stability is a major problem that remains to be addressed.

In this project, a new prismatic stabilization design, named Sleekform and commercialised by Safilens, has been tested in twelve patients with 0.75 or more astigmatic diopters in one or both eyes. The main advantages of this design are the limitation of the mechanical strain and a more regular distribution of the oxygen flow due to its uniform surface.

In order to decide whether the stabilization was good enough or not, refraction and topography exams were undertaken in an initial stage with the objective of choosing the most suitable lens from a set of trial contact lenses without sphere.
After that, different parameters were measured and analysed such as initial position, rotation and the push up.

Sleekform design seemed to be a promising option in the treatment of astigmatism with soft contact lenses but a comparative study with other option/s would be necessary to provide conclusive results.

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RESUM

Español

Actualmente existe una necesidad real de diseño de sistemas de estabilización efectivos para las lentes de contacto tóricas, que garanticen una visión cómoda y nítida a los usuarios.
Aun así, a pesar de los importantes avances que se han realizado en los últimos años, la estabilidad rotacional sigue siendo un punto clave que debe ser abordado.

En este proyecto se ha testado en doce pacientes, con 0,75 o más dioptrías de astigmatismo en uno o ambos ojos, un nuevo diseño de sistema de estabilización prismático llamado Sleekform y comercializado por Safilens.
Las principales ventajas de este diseño son por un lado la limitación de las tensiones mecánicas, y por otro la distribución más regular del flujo de oxígeno gracias a su superficie uniforme.

Con la finalidad de decidir si la estabilización de este tipo de lentes de contacto era buena, se realizaron exámenes refractivos y topografías al inicio del proceso para lograr escoger la lente más adecuada para cada paciente de la batería de lentes de prueba con la que se contaba.
En este caso, ninguna de las lentes de prueba tenía esfera.
A continuación, se midieron y analizaron diversos parámetros como la posición inicial, la rotación o el *push up.*

Sleekform parece ser una opción prometedora en el tratamiento del astigmatismo con lentes de contacto blandas, pero sería necesario un estudio comparativo con otras opciones para proporcionar resultados concluyentes.

GRAU EN OPTICA I OPTOMETRIA

A CLINICAL INVESTIGATION TO STUDY THE PRISMATIC STABILIZATION SYSTEM IN ASTIGMATIC SOFT CONTACT LENSES

RESUM

Català

Avui en dia, existeix una necessitat real de sistemes d'estabilització efectius per a les lents de contacte tòriques, que garanteixin una visió còmode i nítida als usuaris.
Tot i això, malgrat que s'han fet importants avenços en els darrers anys, l'estabilitat rotacional segueix sent un problema necessari d'abordar.

En aquest projecte, es va testar un nou sistema d'estabilització prismàtica en dotze pacients que presentaven 0,75 o més diòptries prismàtics en un o ambdós ulls, anomenat Sleekform i comercialitzat per Safilens. Els principals avantatges d'aquest disseny són la limitació de les tensions mecàniques i la distribució més regular del flux d'oxigen, que s'aconsegueixen gràcies a la seva superfície més uniforme.

Amb la finalitat de decidir si l'estabilització era bona, es van realitzar exàmens refractius i topografies a l'inici per tal de triar la lents de proba més adequada de la bateria disponible. S'ha de destacar que aquestes lents no tenien esfera.
Després es van mesurar i analitzar diferents paràmetres com la posició inicial, la rotació o el *push up.*

El disseny Sleekform, sembla ser una opció prometedora en el tractament de l'astigmatisme amb lents de contacte toves, però per a poder donar resultats concloents seria necessari dur a terme un estudi comparatiu amb una altra opció.

A clinical investigation to study the prismatic stabilization system in astigmatic soft contact lenses

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1. Introduction

Astigmatism is a common type of refractive error in which the eye fails to focus light equally on the retina, leading to blurred vision.

This problem can be caused by deformation of the eyeball (cornea) or eye lens and supposes an inability to form a clear image of two perpendicular lines simultaneously.

1.Normal eye, 2.Irregular cornea, 3.Irregular lens

These different origins cause two types of astigmatism: corneal and refractive astigmatism. Corneal astigmatism comes from the difference in corneal curvature and refractive astigmatism results from the combination of the lenticular and corneal astigmatism.

Treatment options may include surgery and corrective lenses such as glasses or toric contact lenses.

Some contact lens users can be fitted with spherical lenses but if they have significant astigmatism (≥ 0.75 DC), they won't be able to do that.

When fitting astigmatic contact lenses, practitioners must consider the type of the astigmatism in order to choose the most suitable material (GP or soft). Soft contact lenses represent an easier and more comfortable option compared to the GP ones. Furthermore, they are able to correct the refractive astigmatism no matter the appearance of the cornea.

Since the commercial appearance of toric soft contact lenses, significant improvements have been made in terms of material permeability, reproducibility and replacement. Despite this, stabilization is a major problem that remains to be addressed and has a big impact on the visual quality.

Complaints about blurred or fluctuating vision may stem from different causes such as the interaction of the eyelids with the lens while blinking, a deficient rotational stability of the lens or the lens shifting during head movements.

For this reason, there is a real need for effective systems that enable a comfortable and sharp vision in users of astigmatic contact lenses.

2. Aim

The aim of this research project is to test one of the main stabilizations systems employed in commercial soft contact lenses: prismatic.

In order to do that, objective/subjective tests and techniques will be used to characterize the stability during natural viewing conditions.

3. Stabilizing lens rotation: a short review

The main objectives of stabilizing lens rotation are to position the correcting cylinder at the appropriate axis and to minimize rotation during or after a blink, in order to ensure consistent visual performance.

Several methods have been used to stabilize on-eye lens rotation, but the most used commercial methods are the dynamic (also known as thin zone or double slab off) and prismatic stabilization systems (prism ballast and peri-ballast).

In this case, a prismatic design was chosen due to it's consolidated manufacturing system, which makes these type of lenses the most commonly available (for both positive and negative powers). However, it is often advisable to use a dynamic stabilization when just one lens is going to be fitted. This avoids vertical binocular imbalance, especially in patients with vertical phoria problems.

4. Materials and Methods

4.1. Materials

One type of commercial contact lens was assessed, Sleekform developed by Safilens. They have a new design using a pure prism stabilization system that helps reduce thickness keeping a uniform surface. This results in a limitation of the mechanical strain and a more regular distribution of the oxygen flow. These lenses were indicated for single use (daily disposable wear).

The diameter and radius of the trial contact lenses were 14,4 and 8,5 mm respectively. Their material is Filcon IV which contains 40% of water.

A cleaning solution suitable for these types of contact lenses was provided to the participants: *Universale Multiaction Plus* from Schalcon Clear Vision.

A small-cone placido disc topographer, model *Optikon Keratron Onda*, was chosen to obtain the corneal topography. The curvature and shape characteristics of the cornea were used for both the study of the corneal astigmatism and the perfection of the contact lens fitting.

The evaluation of the contact lenses stabilization was realized with a slit-lamp biomicroscope, model *Takagi SM-70N*, linked to a video imaging system which recorded the different tests.

The study was undertaken in the Didactic Clinic of the Materials Science Department in the *Università degli Studi di Milano-Bicocca,* building U9.

4.2. Methods

The main inclusion standard was the level of astigmatism in order to be able to test astigmatic contact lenses.

For this reason, participants with 0.75 or more astigmatic diopters (in one or both eyes) were recruited. At the end of this preliminary stage, 12 subjects started to take part in the study.

After this preliminary part, refraction and topography exams were performed. This process allowed the collection of suitable data to establish; firstly the patient's refractive error and second, to distribute them into different groups according to their refraction.

Once every patient was stratified to a group, a study lens was trialled in each eye for one session in which different tests were done to assess their stability. These were the initial position, the rotation test and the push up test. The results were recorded by the camera linked to the slit lamp.

Before starting the exam, the participants had to wait 20 minutes with the lens on the eye. Once used, all the contact lenses were discarded.

5. Results and discussion

According to the inclusion criteria, the study consisted of a total of 12 right eyes and 8 left eyes of 12 patients with a mean age of 22 years old. The 25% of the subjects were male while the 75% were female.

5.1. Refraction

The results obtained after the refraction tests were the following ones:

Patient	Rx OD	Rx OI
1	-0,25 -0,75 x 100º	-0,50 x 30º
2	-2,25 -1,25 x 100º	-3,00 -0,50 x 70º
3	+4,25 -3,75 x180º	+3,75-4,00 x10º
4	+3,75-1,00 x 175º	+4,50-1,75 x 180º
5	+3,25-1,50 x175º	+3,50-1,50x180º
6	+1,00-1,75 x5º	-1,75
7	-5,50-1,50x180º	-5,50-1,00x180º
8	-0,50-1,00x93º	-0,75
9	-5,00-1,25x180º	-4,25-1,50x170º
10	-2,00-3,00x180º	-3,25-3,00x180º
11	-1,00-0,75x30º	-0,50-0,50x170º
12	-2,50-0,75x90º	-2,75-0,75x100º

Table 1. Results of refraction tests

Not all the subjects were regular users of contact lenses. In the table below *(table 2)*, it shows the patients that had experience using contact lenses and the refractions that they had.

Patient	Usual LC Rx OD	Usual LC RX OI
1	N	N
2	-2,25 -1,25 x 100º	-3,00
3	N	N
4	+4,00-1,25 x 175º	+4,50-1,75 x 180º
5	+3,00-1,50 x180º	+3,00-1,50 x10º
6	+1,50-1,75 x180º	-1,25
7	-5,50 -1,25 x180º	-5,50 -1,25 x180º
8	-0,50-1,00x90º	-0,75
9	-5,00	-4,00
10	-1,75-2.75x180º	-3,25-2,75x180º
11	N	N
12	-2,00*	-2,25*

Table 2. Refractions worn in previous contact lenses

Considering the results obtained in both Table 1 and Table 2 and vertexing the spectacle lens power to the corneal plane, the most appropriate refractive error in contact lenses was proposed

But, since the objective in this study was to assess the stability of the contact lenses and not the quality of the vision, a battery of trial lenses without sphere was chosen.

This battery included eight different axis (15º,30º,75º,90º,105º,150º,165º,180º) and three possible refractive errors -1,00, -1.50 and -2.00 astigmatic diopters. The previous values were converted into refractive errors from the trial battery using a resemblance approach.

At this point, two of the patients (patient 2 and 3) left the trial due to personal reasons and as a consequence, they were not included in the last table.

Finally, the contact lenses chosen from the battery for each patient were the following ones:

Patient	Usual LC Rx OD	Usual LC RX OI
1	-0,00-1,00x105º	
2		
3		
4	-0,00-1,00x180	-0,00-1,50x165
5	+0,00-1,50x165º	+0,00-1,50x180º
6	+0,00-2,00x180º	
7	-0,00-1,50x180º	-0,00-1,00x180º
8	-0,00-1,00x90º	
9	-0,00-1,50x180	-0,00-1,50x165
10	-0,00-2,00x180º	-0,00-2,00x180º
11	-0,00-1,00x30º	-0,00-1,00x165
12	-0,00-1,00x90	-0,00-1,00x105

Table 3. Trial contact lenses chosen

5.2. Topography

It is important to consider that corneal topography measures, among other parameters, the corneal astigmatism. Because of this, the topography results do not necessary have to be the same ones as the refraction.

The topography was undertaken in the eyes with refractive astigmatism matching the inclusion criteria (≥0,75D). Besides, each eye was analysed eight times in order to obtain representative results and the repeatability was checked using the software Keratron Scout.

As mentioned before, in this case a Placido disc small cone topographer was used, which projects more rings (28) on the cornea than a large cone topographer and avoids reflection of anatomical structures like the nose or eyebrows. The main disadvantage is that more stability is needed to obtain an accurate image, so blurred captures and outliers were discarded.

The statistical descriptors were obtained using the SPSS Statistical Program.

Unites of the parameters are the following ones: mm (radius), D (corneal astigmatism, TI and SimK) and nondimensional (TI).

Patient 1

OD (N=7)	$\overline{X}$ ± sd	Range
Radius	8,20±0,13	7-8,6
TI (topographic irregularity)	0,22±0,05	0,4±0,2
Sim K	41,0±0,16	<47,20D
CLMI (Cone location and Magnitude Index)	0,58±0,19	<3,00
Corneal Astigmatism	-0,72±0,15	-

Table 4. Topography results for patient 1

Patient 4

OD (N=7)	$\overline{X}$ ± sd	Range
Radius	8,20±0,13	7-8,6
TI (topographic irregularity)	0,35±0,07	0,4±0,2
Sim K	44,55±0,77	<47,20D
CLMI (Cone location and Magnitude Index)	1,75±0,12	<3,00
Corneal Astigmatism	-2,28±0,08	-

OI (N=7)	$\overline{X}$ ± sd	Range
Radius	7,72±0,05	7-8,6
TI (topographic irregularity)	0,20±0,13	0,4±0,2
Sim K	45,650±1,20	<47,20D
CLMI (Cone location and Magnitude Index)	1,77±0,53	<3,00
Corneal Astigmatism	-2,75±0,14	-

Table 5-6. Topography results for patient 4

Patient 5

OD (N=6)	$\bar{X}$ ± sd	Range
Radius	7,99±0,05	7-8,6
TI (topographic irregularity)	0,60±0,18	0,4±0,2
Sim K	43,4±1,0	<47,20D
CLMI (Cone location and Magnitude Index)	2,05±0,25	<3,00
Corneal Astigmatism	1,41±0,15	-

OI (N=8)	$\bar{X}$ ± sd	Range
Radius	8,28±0,13	7-8,6
TI (topographic irregularity)	0.45±0.09	0,4±0,2
Sim K	42,62±0.9	<47,20D
CLMI (Cone location and Magnitude Index)	1,93±0,11	<3,00
Corneal Astigmatism	-1,15±0.09	-

Table 7-8. Topography results for patient 5

Patient 6

OD (N=8)	$\bar{X}$ ± sd	Range
Radius	7,40±0,08	7-8,6
TI (topographic irregularity)	0,28±0,09	0,4±0,2
Sim K	46,00±0,41	<47,20D
CLMI (Cone location and Magnitude Index)	1,00±0,11	<3,00
Corneal Astigmatism	-1,75±0,12	-

Table 9. Topography results for patient 6

Patient 7

OD (N=8)	$\bar{X}$ ± sd	Range
Radius	7,97±0,14	7-8,6
TI (topographic irregularity)	0,34±0,19	0,4±0,2
Sim K	42,0±0,27	<47,20D
CLMI (Cone location and Magnitude Index)	0,48±0,22	<3,00
Corneal Astigmatism	-1,81±0,03	-

OI (N=4)	$\bar{X}$ ± sd	Range
Radius	8,24±0,04	7-8,6
TI (topographic irregularity)	0,38±0,07	0,4±0,2
Sim K	42,75±0,31	<47,20D
CLMI (Cone location and Magnitude Index)	0,25±0,07	<3,00
Corneal Astigmatism	-1,78±0,20	-

Table 10-11. Topography results for patient 7

Patient 8

OD (N=7)	$\bar{X}$ ± sd	Range
Radius	7,92±0,05	7-8,6
TI (topographic irregularity)	0,33±0,06	0,4±0,2
Sim K	44,51±0,28	<47,20D
CLMI (Cone location and Magnitude Index)	0,8±0,26	<3,00
Corneal Astigmatism	-0,55±0,09	-

Table 12. Topography results for patient 8

Patient 9

OD (N=7)	$\bar{X}$ ± sd	Range
Radius	7,23±0,9	7-8,6
TI (topographic irregularity)	0,32±0,09	0,4±0,2
Sim K	46,85±0,15	<47,20D
CLMI (Cone location and Magnitude Index)	0,27±0,07	<3,00
Corneal Astigmatism	-1,41±0,13	-

OI (N=3)	$\bar{X}$ ± sd	Range
Radius	7,32±0,08	7-8,6
TI (topographic irregularity)	0,24±0,05	0,4±0,2
Sim K	46,06±0,13	<47,20D
CLMI (Cone location and Magnitude Index)	0,24±0,06	<3,00
Corneal Astigmatism	-1,55±0,05	-

Table 13-14. Topography results for patient 9

Patient 10

OD (N=8)	$\bar{X}$ ± sd	Range
Radius	7,61±0,07	7-8,6
TI (topographic irregularity)	0,25±0,09	0.4±0.2
Sim K	44,0±0,11	<47,20D
CLMI (Cone location and Magnitude Index)	0,34±0,34	<3,00
Corneal Astigmatism	-2,75±0,15	-

OI (N=8)	$\bar{X}$ ± sd	Range
Radius	7,66±0,17	7-8,6
TI (topographic irregularity)	0,34±0,08	0.4±0.2
Sim K	43,95±0,10	<47,20D
CLMI (Cone location and Magnitude Index)	0,39±0,23	<3,00
Corneal Astigmatism	-2,98±0,09	-

Table 15-16. Topography results for patient 10

Patient 11

OD (N=3)	$\bar{X}$ ± sd	Range
Radius	7,55±0,05	7-8,6
TI (topographic irregularity)	0,54±0,29	0.4±0.2
Sim K	45,61±0,20	<47,20D
CLMI (Cone location and Magnitude Index)	1,52±0,57	<3,00
Corneal Astigmatism	-1,15±0,10	-

OI (N=5)	$\bar{X}$ ± sd	Range
Radius	7,44±0,16	7-8,6
TI (topographic irregularity)	0,28±0,08	0.4±0.2
Sim K	45,48±0,21	<47,20D
CLMI (Cone location and Magnitude Index)	0,97±0,48	<3,00
Corneal Astigmatism	-1,27±0,23	-

Table 17-18. Topography results for patient 11

Patient 12

OD (N=3)	$\bar{X}$ ± sd	Range
Radius	7,56±0,03	7-8,6
TI (topographic irregularity)	0,19±0,09	0,4±0,2
Sim K	46,0±0,09	<47,20D
CLMI (Cone location and Magnitude Index)	0,6±0,27	<3,00
Corneal Astigmatism	0,27±0,06	-

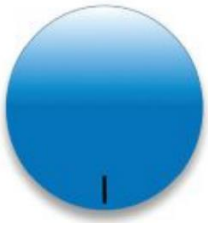
OI (N=5)	$\bar{X}$ ± sd	Range
Radius	7,42±0,07	7-8,6
TI (topographic irregularity)	0,6±0,06	0,4±0,2
Sim K	45,90±0,13	<47,20D
CLMI (Cone location and Magnitude Index)	0,97±0,07	<3,00
Corneal Astigmatism	0,29±0,08	-

Table 19-20. Topography results for patient 12

The different parameters calculated were inside the normal range. Corneal and refractive astigmatism were the same in patients 1, 5,6,9 and 10 and different in all others due to other ocular structures apart from the cornea.

5.3. Stability evaluation

Different parameters were measured to evaluate the stability of the contact lenses in the eye. These were; initial position, rotation test and push up test. This could be done thanks to the marks included at the central inferior portion of the lens (at 6 o'clock).



All trial lenses had the same radius and diameter, so that justifies some of the differences between patients considering their ocular parameters were different.

5.3.1. Initial position

The initial position was acceptable in general. Focusing on the centration, in most of the cases there was full corneal coverage in primary gaze and in all gaze positions.

Patient	Parameters Analysis	
	OD (º)	OI (º)
1	0	
4	10º T	5º N
5	0	10º N
6	15º N	
7	10º T	10º N
8	10 º N	
9	10º T	10º N
10	0	20º T
11	5º N	0
12	0	5º T

* *N (Nasal), T (Temporal*).*Table 21. Misalignments*

The findings on the table reveal some misalignment, however on the basis that one-third part of the cylinder power is not corrected every 10º, the importance of these findings is not crucial in these patients with low and medium astigmatisms.

5.3.2. Rotation test

The results were determined visually with the video recorded by the slit lamp and measured in seconds.

Patient	Parameters Analysis	
	OD (seconds)	OI (seconds)
1	14	
4	12	7
5	8	8
6	20	
7	9	7
8	10	
9	9	8
10	11	25
11	7	8
12	15	9

Table 22. Rotation test results

5.3.3. Push up test

Push up test is an effective way to asses the dynamic fit of the lens.

It consists of applying a smooth pressure in the lower eyelid with the objective of moving the lens vertically and analysing the recovery speed to the initial position.

It has been proposed a percentage grade, in which 100 per cent represents an unmovable lens and 0 per cent a lens that falls without lid support. The optimal lens fitting would get a 50 percent punctuation. Results were assessed and ranged visually.

Patient	Parameters Analysis	
	OD (%)	OI (%)
1	65	
4	45	60
5	60	50
6	65	
7	40	40
8	40	
9	35	60
10	50	65
11	45	50
12	55	60

Table 23. Push up test results

In general, there was no poor movement in any of the cases. If that would have happened, this lens should be rejected in that patient.

6. Conclusions

It is important to outline that both the power and the axis were similar but didn't completely match the refraction in some of the patients. Despite this fact, that could explain the misalignment in certain cases, the results were satisfactory.

In conclusion, this new design seems a promising option in the stabilization of astigmatic soft contact lenses. However, further research is required, preferably a comparative study.

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